



Healthcare
Improvement
Scotland

Inspections
and reviews
To drive improvement

Announced Inspection Report – Ionising Radiation (Medical Exposure) Regulations 2017

Aberdeen Royal Infirmary
NHS Grampian

3-4 August 2021

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About our IR(ME)R inspections

Our approach

Healthcare Improvement Scotland has a statutory responsibility to provide public assurance about the quality and safety of healthcare through its inspection activity.

The quality of care approach and the quality framework together allows us to provide external assurance of the quality of healthcare provided in Scotland.

- **The quality of care approach** brings a consistency to our quality assurance activity by basing all of our inspections and reviews on a set of fundamental principles and a common quality framework.
- **Our quality framework** has been aligned to the Scottish Government's *Health and Social Care Standards: My support, my life* (June 2017). These standards apply to the NHS, as well as independent services registered with Healthcare Improvement. They set out what anyone should expect when using health, social care or social work services.

We have aligned the Ionising Radiation (Medical Exposure) Regulations 2017, referred to as IR(ME)R, to the quality framework.

How we inspect services that use ionising radiation for medical exposure

The focus of our inspections is to ensure each service is implementing the IR(ME)R 2017. Therefore, we only evaluate the service against quality indicators that align to the regulations.

What we look at

We want to find out:

- How the service complies with its legal obligations under IR(ME)R 2017 and address the radiation protection of persons undergoing medical exposures.
- How well services are led, managed and delivered.

After our inspections, we publish a report on how well a service is complying with IR(ME)R and its performance against the Healthcare Improvement Scotland quality framework.

More information about the quality framework and quality of care approach can be found on our website:

www.healthcareimprovementscotland.org/our_work/governance_and_assurance/quality_of_care_approach.aspx

Summary of inspection

About our inspection

We carried out an announced inspection to the Aberdeen Royal Infirmary, NHS Grampian, on Tuesday 3 and Wednesday 4 August 2021. We spoke with a number of staff including the medical director, who is the IR(ME)R lead, radiologists, radiographers and medical physics experts. The inspection team was made up of two inspectors.

Aberdeen Royal Infirmary offers a variety of diagnostic imaging using ionising radiation such as plain film, computerised tomography (CT) and mammography. It also provides nuclear medicine services and radiotherapy. The focus of this inspection was diagnostic imaging on the radiology department. NHS Grampian undertake 50,000 CT examinations and 180,000 plain film examinations.

What we found

What the service did well

- Effective governance arrangements are in place and strong leadership supports the implementation of IR(ME)R.
- Radiographers confirm clinical details provided by the referrer, such as the placement of a nasogastric tube.
- Employer's procedures are well structured and clear.
- NHS Grampian have developed an IR(ME)R specific online training module as part of their continual professional development for radiology staff.

What the service needs to improve

- All referring GPs must be individually entitled.
- Develop its employer's procedures to include the scope of audit for all contracted radiology services.

Detailed findings from our inspection can be found on page 8.

What action we expect NHS Grampian to take after our inspection

This inspection resulted in two requirements and six recommendations. Requirements are linked to compliance with IR(ME)R. See Appendix 1 for a full list of the requirements and recommendations.

An improvement action plan has been developed by the NHS board and is available on the Healthcare Improvement Scotland website.

https://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/ionising_radiation_regulation.aspx.

NHS Grampian must address the requirements and make the necessary improvements as a matter of priority.

We would like to thank all staff at the radiology department of Aberdeen Royal Infirmary for their assistance during the inspection.

What we found during our inspection

Outcomes and impact

This section is where we report on what key outcomes the service has achieved and how well the service meets people's needs.

Domain 1 – Key organisational outcomes

High performing healthcare organisations identify and monitor key measures that help determine the quality of service delivery and the impact on those who use the service or work with the service.

IR(ME)R requires that those who refer for a patient to be exposed to medical radiation, those who operate equipment and those healthcare professionals (medical and non-medical) who justify that the procedure is necessary, must be adequately trained and entitled to do so. Entitlement is given to each person involved in the process by the employer.

What we found - fulfilment of statutory duties and adherence to national guidelines

Entitlement

The process of entitlement sets out the scope of practice that an individual can carry out, such as the types of referrals, operate equipment and undertake clinical evaluations. Their scope of practice depends on the individual's qualifications, role, training and experience. It can also change over time, following additional training or moving to a new role. The individual is required to work within this scope of practice. Employer's procedures also include what should be included in the scope of practice for each staff group.

All radiologists who are Fellows of the Royal College of Radiologists are entitled to carry out justifications and clinical evaluations. A radiologist is a doctor who is specially trained to interpret diagnostic images such as X-rays and CT scans.

Radiographers, depending on their training, are entitled to act as operators and carry out justifications and clinical evaluations of plain film x-rays.

Another group of staff who are entitled to make referrals are non-medical referrers, healthcare professionals who are not doctors or dentists. A non-medical referrer must have the support of their clinical lead before they apply. They must also complete an IR(ME)R specific online training module.

Applications are approved by the departmental responsible person (radiology IR(ME)R lead).

A list of approximately 450 non-medical referrers is available on the NHS board's intranet. However, it does not include details of individuals' scope of practice. Non-medical referrers must reapply every 3 years to retain their entitlement. They must also contact the radiology department, through a dedicated mailbox, with any changes to their circumstances. Such as, moving to a new role that changes their need to refer.

We are assured that NHS Grampian has clear processes and procedures in place to demonstrate that the approval of non-medical referrers' entitlement is appropriately managed.

Referral

A referral can only be made by a person who is entitled to do so. Referrals will come into the radiology department from a variety of sources, both within the hospital and from the community. Referrals are made internally through the electronic radiology information system. External referrals are received by email or on a paper form. These referrals are scanned into the radiology information system by the administrative staff.

Justification

Radiologists and radiographers review all referrals, within their scope of practice, to ensure there is sufficient information to be able to justify the referral. They will take into consideration the risks and benefits for the patient and consider non-ionising radiation options where possible. They will also check whether any previous imaging has been undertaken and duplicate referrals. If insufficient clinical information has been received, or it is not considered appropriate, the referral will be rejected and the referrer informed.

Any referrals for unscheduled exposures are reviewed and justified on the day. All referrals for planned exposures (by appointment) will be justified in advance of the appointment.

Records

We looked at the information recorded on the radiography information system and noted staff had documented the following:

- correct patient information
- identification checks
- scanned documents, such as pregnancy check questionnaires
- details of the referrer and operator

- recorded dose
- justification, and
- clinical evaluation.

Radiography staff could describe the checks they would undertake prior to recording information and where they would get the dose information.

Employer's procedure RA5 (Carrying out x-ray exposures and dose optimisation) provides guidance for staff to confirm clinical information provided by the referrer, when required. For example, checking a nasogastric is in place or pacemaker is inserted to avoid unnecessary exposures if they are not in place.

What needs to improve

NHS Grampian currently entitle GP referrers as a group, as set out in EP2 (Entitlement and responsibilities of Medical and Dental Referrers for diagnostic exposures) (requirement 1).

On reviewing records on the radiography information system, we noted trainee radiographers' details were not always recorded. A trainee, depending on their level of training, may have a more involved role in delivering the examination and it is important that their details are recorded (recommendation a).

The spreadsheet of non-medical referrers does not include details of individuals' scope of practice. Radiography staff are therefore unable to confirm a non-medical referrers' scope of practice as part of their checks. Currently they rely on personal knowledge of non-medical referrers (recommendation b).

Requirement 1

- NHS Grampian must entitle individual GPs to allow them to make referrals.

Recommendation a

- NHS Grampian should ensure that trainee radiographers' details are recorded on the radiography information system when they are part of the imaging team when an exposure is carried.

Recommendation b

- NHS Grampian should ensure the spreadsheet of non-medical referrers includes details of each individual's scope of practice. This will allow radiographers to check that a non-medical referrer is entitled to make the referral.

Service delivery

This section is where we report on how well the service is delivered and managed.

Domain 5 – Safe, effective and person-centred care delivery

High performing healthcare organisations are focused on safety and learning to take forward improvements, and put in place appropriate controls to manage risks. They provide care that is respectful and responsive to people’s individual needs, preferences and values delivered through appropriate clinical and operational planning, processes and procedures.

What we found - safe delivery of care

Safety culture

We spoke with the IR(ME)R lead (medical director), radiology departmental responsible person for IR(ME)R (radiology IR(ME)R lead), superintendent radiographers, radiographers and medical physics experts who were all positive about the safety culture within the radiology department. Radiology staff told us about the positive culture for reporting and learning from incidents. They also told us of the collaborative learning environment. We were told:

- the culture is open and transparent, and
- staff are encouraged to speak up – it’s all about the learning.

Employer’s procedures

NHS Grampian has a duty under IR(ME)R to develop written procedures commonly referred to as employer’s procedures. These are intended to provide a framework under which professionals can practise. NHS Grampian has a clear structure for the development and update of its employer’s procedures. The NHS board has three levels of employer’s procedures:

- level 1 applies to the whole NHS board, including all modalities
- level 2 are modality specific across various sites, and
- level 3 are department protocols.

The employer’s procedures we reviewed were all clear, up to date and cross referenced. All staff we spoke with were familiar with the employer’s procedures and could find them easily. Updates are communicated to staff through emails and staff meetings.

Patient identification

NHS Grampian's employer's procedure RA3 (Identification of patients) provides guidance on patient identification checks.

All the radiographers we spoke with could clearly describe how they carry out identity checks and they are familiar with the relevant employer's procedures. They told us they would ask the patient their name, date of birth and one further identification check prior to any exposures. All inpatients must also have a wrist band in place. An exposure would not proceed if the patient identification checks were not complete.

Risk benefit conversations

Employer's procedure RA13 (Provision of information relating to the benefits and risks of an exposure) details the procedure for providing information on the risks and benefits associated with the radiation dose from medical exposure. Patients are provided with information on risks and benefits prior to a scheduled appointment.

We saw information posters displayed in the radiology department and in changing facilities to inform patients of the low risk of an exposure. The posters also highlight the need to inform a member of staff of any possibility they may be pregnant.

Making enquiries of individuals who could be pregnant

Employer's procedure RA4 (Making enquiries of pregnancy status) details the procedure when considering if a person, who is of child bearing age, is to be exposed to ionising radiation, may be pregnant. Patients will be asked the pregnancy status questions by the radiographer at the time of the examination – we saw answers were recorded in the radiography information system. If a patient is unsure about their pregnancy status, they will usually be asked to come back when they can confirm they are not pregnant. When an individual is confirmed to be pregnant and the exposure is to go ahead, the correct documentation must be in place.

Employer's procedure RA4 includes a record that must be signed by the referrer and practitioner confirming the patient's pregnancy status and that discussion of risks and benefits has taken place. Radiographers will not proceed with the exposure without this documentation.

All staff we spoke with were clear on the procedure. Radiologists confirmed they support referrers to make a decision about whether to proceed with an exposure and they would always consider non-ionising radiation options, when possible.

Carers and comforters procedures

NHS Grampian has clear guidance on the authorisation of an exposure to a carer or comforter, such as the mother of a child. All staff could describe the measures they would take to encourage carers and comforters to leave the room, if possible, and how to reduce their exposure if not. Carers and comforters would be directed to the available patient information prior to any exposure. Dose constraints for carers and comforters are in place.

General duties in relation to equipment

NHS Grampian are moving to a single equipment register that combines details of the ongoing quality assurance, audits and maintenance of all equipment. It includes details about the location, serial number and age of the equipment. The register can be used to identify equipment that is reaching its end of life.

NHS Grampian's equipment medical devices group reviews requests for replacement equipment made by radiography managers. Requests include the age of the equipment, previous quality assurance checks and dose data. We saw NHS Grampian have CT scanners between 9 and 12 years old. Plans are in place to replace the oldest equipment.

All equipment subject to IR(ME)R is required to be included in a quality assurance programme, which monitors equipment performance and ensures operation is within agreed dose levels. A variety of quality assurance checks are carried out by radiography staff either daily, weekly and monthly. Staff were able to describe the process when a piece of equipment fails a quality assurance check. This includes asking for support from the medical physics experts and calling the engineer out to repair a piece of equipment.

When an engineer repairs x-ray equipment, quality assurance is carried out by radiographers prior to it being put back into service if the engineer indicates it is required. Radiographers in the CT department carry out quality assurance checks before any equipment is put back into service, following a visit by engineers. All staff could describe this handover procedure and up-to-date records were available. We saw handovers sheets and audit records were also up to date.

Accidental or unintended exposure

Employer's procedure RA10 (Reporting adverse radiation events and near misses) provides guidance on reporting incidents. It provides information on roles and responsibilities, how to carry out an investigation, the reporting mechanism and how to ensure the investigation has been carried out appropriately.

The guidance also highlights the need to report near misses and the criteria for making statutory notifications. The medical physics experts provide support for individuals undertaking an investigation.

All staff we spoke with could describe the positive culture of reporting near misses and incidents. We were told that learning from near misses and incidents is shared to help prevent incidents in the future.

Optimisation

Dose optimisation is the balance between the lowest dose and the image quality that is clinically suitable. Local dose reference levels are detailed in employer's procedure RA9 (Assessing patient dose and dose audit), which all staff are aware of. Dose reference levels were also displayed near equipment in the radiology department.

Medical physics experts use dose audit information to set local dose reference levels. Where local dose reference levels are not available, NHS Grampian can use UK or European dose reference levels. Dose optimisation is carried out at the installation and commissioning stage. Thereafter equipment dose reference levels are regularly reviewed and updated.

NHS Grampian's multidisciplinary dose optimisation group reviews local dose reference levels. The group is working towards reducing patient dose while still producing clinically effective images. This group have recently carried out a review of head CT dose data for paediatric patients, which has resulted in the development of a protocol with the recommended use of a specific CT scanner with the lowest dose, whenever possible.

The equipment used to expose patients to ionising radiation have a variety of protocols that help deliver standardised exposures. Exposures can be modified for adults and children and take account of different body sizes. All operators we spoke with could describe how they would select the correct protocol for the intended purpose. Radiologists we spoke with told us how they calculate image quality with as low a dose as was reasonably practical when justifying an exposure. They would always consider an alternative to ionising radiation if possible.

What needs to improve

While we saw quality assurance checks were being carried out for all plain film equipment before being put back into service, radiographers only carry out quality assurance checks on CT equipment when advised to do so (recommendation c).

- No requirements.

Recommendation c

- NHS Grampian should ensure radiographers are aware when quality assurance checks should be carried out on equipment, following an engineer visit.

Domain 6 – Policies, planning and governance

High performing healthcare organisations translate strategy into operational delivery through development and reliable implementation of plans and policies, and have effective accountability, governance and performance management systems in place.

Each organisation must appoint an IR(ME)R lead who is responsible for the implementation of systems and processes to ensure statutory requirements are being met. There must be clear governance processes in place to demonstrate that IR(ME)R is managed and implemented.

What we found - policies and procedures

NHS Grampian's IR(ME)R policy provides clear structure about how IR(ME)R is implemented. It includes the roles and responsibilities from the chief executive to department staff. The IR(ME)R lead (medical director), who is appointed by the chief executive, is responsible for ensuring that the IR(ME)R policy is implemented.

What we found - risk management, audit and governance

The IR(ME)R lead has a good understanding of their role and responsibilities under IR(ME)R. They link with the chief executive and report to the clinical and care governance group. The IR(ME)R lead entitles all the medical staff and medical physics experts, in line with the employer's procedure. They told us they felt supported in their role by the radiation protection team.

The IR(ME)R lead appoints all departmental responsible persons (in radiology this would be the lead radiologist) who are responsible for the ongoing implementation of IR(ME)R in each department, as set out in IR(ME)R policy.

NHS Grampian's radiation safety committee, chaired by the IR(ME)R lead, provides oversight for the implementation of IR(ME)R and assurance that the NHS board is meeting its statutory obligations. For example, the group previously discussed the process of entitlement and whether IR(ME)R training should be mandatory for all referrers.

Other groups that support the implementation of IR(ME)R in the radiology department include:

- a radiology IR(ME)R group that meets every 2 weeks
- a radiology radiation protection supervisor group that meets every 8 weeks, and
- modality groups that meet every month, including plain film and CT.

Group membership is from a variety of professions including radiologist, radiographer managers and medical physic experts. Each group has its own escalation route. They have been working on standardising procedures across NHS Grampian. This includes removing level 3 employer's procedures (department protocols) and incorporating them into level 2 procedures (modality procedures) to improve consistency.

All staff groups we spoke with were positive about the different groups and that IR(ME)R was a standing agenda item at many of them. They felt there was sufficient opportunity to share information relating to IR(ME)R.

Contracted services

NHS Grampian use a private company to undertake clinical evaluations and justifications. The unit clinical director (lead radiologist) and unit operational manager provide oversight of the private company.

All radiologists provided by the private company must be registered with the General Medical Council. Individual radiologists' details are recorded against each clinical evaluation carried out.

The private company carries out its own quality assurance and results are provided to NHS Grampian.

Clinical audit

Employer's procedure EP3 (Departmental IR(ME)R audit and clinical audit) details the audit activity relating to IR(ME)R. Audits are completed by each department every 2 years and results are submitted to the radiation safety committee. The scope of audits cover:

- entitlement
- training records to support entitlement
- referrals
- justifications

- clinical evaluations
- appointment of medical physics experts
- all written procedures
- incidents, and
- dose.

We were told that audits have been undertaken in the following areas:

- whether clinical evaluations were in place in the emergency department and orthopaedics
- ensuring appropriate justifications for CT referrals, and
- whether wrist bands were in place for emergency department patients.

What needs to improve

No processes were in place to independently audit clinical evaluations provided by the private company (requirement 2).

We were told that radiologists carry out peer reviews of clinical evaluations as part of their routine practice, however this is not recorded (recommendation d).

NHS Grampian could consider increasing the frequency of audits, as set out in EP3 (Departmental IR(ME)R audit and clinical audit), to provide further assurance on how employer's procedures are being followed.

Requirement 2

- NHS Grampian must develop its employer's procedure to include the scope of clinical audit for contracted radiology services provided private companies. It should include the frequency of audit and identify who should carry them out.

Recommendation d

- NHS Grampian should record peer reviews of clinical evaluations, in line with Royal College of Radiologists quality assurance in radiology reporting guidance.

Domain 7 – Workforce management and support

High performing healthcare organisations have a proactive approach to workforce planning and management, and value their people supporting them to deliver safe and high quality care.

What we found - staff recruitment, training and development

Expert advice

NHS Grampian has less than two whole time equivalent medical physics experts, who are supported by clinical scientists. They also provide support for NHS Orkney and NHS Shetland.

Medical physics experts are appointed by letter by the IR(ME)R lead and provide advice in relation to compliance with IR(ME)R. They are involved in a variety of areas including:

- commissioning of new equipment
- quality assurance of equipment
- dose monitoring
- training, and
- analysis of incidents.

Medical physics experts also provide advice on whether an incident requires to be reported to Healthcare Improvement Scotland.

Staff told us the medical physics experts were easily contactable and available for advice and support.

NHS Grampian carried out a review of the current staffing workforce prior to inspection using the European Federation of Organisations for Medical Physics guidance. This was the first review of medical physics expert workforce since the introduction of IR(ME)R 2017. The guidance indicated a workforce of 3.6 medical physics experts was required.

Training

We found comprehensive training records in place for radiology staff involved in medical exposure to radiation.

Once a radiographer qualifies, NHS Grampian provides an induction and partners them with a senior radiographer for support. We saw records that demonstrated relevant training had been provided.

A radiographer's training record is closely linked to their entitlement. We reviewed a sample of records and saw each individual's entitlement corresponded with their training record. Radiographers are responsible for maintaining their own continual professional development as part of their professional registration. In CT, radiologists review 50 justifications made by radiographers each year. Any learning is fed back to radiographers as part of their ongoing learning.

Operators must be trained on each specific piece of equipment. All radiographers we spoke with told us they had received appropriate training and all training records inspected were up to date.

Radiologist training and continual professional development is managed through their annual appraisals and medical revalidation process every 5 years.

We saw evidence of continual education for radiologists and radiographers. NHS Grampian have developed an IR(ME)R specific online training module that must be completed every 3 years by radiology staff.

Further educational opportunities are provided at post graduate lectures and team meetings. Staff told us they were encouraged to think of their training as part of their day-to-day activities.

Agency staff must meet the same level of training as NHS Grampian staff. Trainee radiographers can only work under the supervision of a qualified radiographer.

What needs to improve

The medical physics expert staffing levels were not included in any workforce planning. The provision of additional medical physics experts will support NHS Grampian to undertake further optimisation work, more reviews of interventional procedures and analysis between different units (recommendation e).

While we saw relevant IR(ME)R specific training taking place for staff within the radiology department, the NHS board does not deliver this training for staff outwith radiology, who have obligations under IR(ME)R. It is considered best practice for referrers to complete some form of local awareness training, where practical (recommendation f).

- No requirements.

Recommendation e

- NHS Grampian should ensure its workforce plans outline the medical physics expert resource required to meet the predicted service need. It should include how the NHS board intends to address the shortfall in staff in the short and long term.

Recommendation f

- NHS Grampian should ensure referrers who work within the scope of IR(ME)R complete local awareness training, such as the NHS Grampian IR(ME)R specific online training module.

Appendix 1 – Requirements and recommendations

The actions that Healthcare Improvement Scotland expects the independent healthcare service to take are called requirements and recommendations.

- **Requirement:** A requirement is a statement which sets out what is required of a service to comply with the Regulations. Requirements are enforceable at the discretion of Healthcare Improvement Scotland.
- **Recommendation:** A recommendation is a statement that sets out actions the service should take to improve or develop the quality of the service but where failure to do so will not directly result in enforcement.

Domain 1 – Key organisational outcomes	
Requirement	
1	NHS Grampian must entitle individual GPs to allow them to make referrals (see page 10). <i>Regulation 17(1) Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendations	
a	NHS Grampian should ensure that trainee radiographers' details are recorded on the radiography information system when they are part of the imaging team when an exposure is carried (see page 10).
b	NHS Grampian should ensure the spreadsheet of non-medical referrers includes details of each individual's scope of practice. This will allow radiographers to check that a non-medical referrer is entitled to make the referral (see page 10).

Domain 5 – Safe, effective and person-centred care delivery	
Requirements	
	None
Recommendation	
c	NHS Grampian should ensure radiographers are aware when quality assurance checks should be carried out on equipment, following an engineer visit (see page 15).

Domain 6 – Policies, planning and governance

Requirement

- 2** NHS Grampian must develop its employer's procedure to include the scope of clinical audit for contracted radiology services provided private companies. It should include the frequency of audit and identify who should carry them out (see page 17).

Regulation 7

Ionising Radiation (Medical Exposure) Regulations 2017

Recommendation

- d** NHS Grampian should record peer reviews of clinical evaluations, in line with Royal College of Radiologists quality assurance in radiology reporting guidance (see page 17).

Domain 7 – Workforce management and support

Requirements

None

Recommendations

- e** NHS Grampian should ensure its workforce plans outline the medical physics expert resource required to meet the predicted service need. It should include how the NHS board intends to address the shortfall in staff in the short and long term (see page 20).
- f** NHS Grampian should ensure referrers who work within the scope of IR(ME)R complete local awareness training, such as the NHS Grampian IR(ME)R specific online training module (see page 20).

Complaints/Concerns

If you would like to raise a concern or complaint regarding any aspect of the inspection then please discuss this with the lead inspector in the first instance.

If there is a concern or complaint about the conduct of an inspector please contact Kevin Freeman-Ferguson, Head of Service Review, kevin.freeman-ferguson@nhs.scot in the first instance to discuss your concerns in more detail.

Alternatively, Healthcare Improvement Scotland has a complaint and feedback service that can be contacted directly. Details can be found on our webpage.

http://www.healthcareimprovementscotland.org/about_us/contact_healthcare_improvement/complaints.aspx

Our contact details are:

Healthcare Improvement Scotland

Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Telephone: 0131 623 4300

Email: his.comments@nhs.scot

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or email contactpublicinvolvement.his@nhs.net

Healthcare Improvement Scotland

Edinburgh Office
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

0131 623 4300

Glasgow Office
Delta House
50 West Nile Street
Glasgow
G1 2NP

0141 225 6999

www.healthcareimprovementscotland.org